CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 126	Date: September 30, 2010
	Change Request 7133

SUBJECT: Counseling to Prevent Tobacco Use

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after August 25, 2010, CMS will cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries:

- 1. Who use tobacco, regardless of whether they have signs or symptoms of tobacco-related disease;
- 2. Who are competent and alert at the time that counseling is provided; and
- 3. Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

These individuals who do not have signs or symptoms of tobacco-related disease will be covered under Medicare Part B when the above conditions of coverage are met, subject to certain frequency and other limitations.

This revision [to the Medicare National Coverage Determinations Manual] is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, [contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: AUGUST 25, 2010 IMPLEMENTATION DATE: JANUARY 3, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated) R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE							
R	1/Table of Contents							
N	1/210.4.1/Counseling to Prevent Tobacco Use (Effective August 25, 2010)							

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

*Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-03 | Transmittal: 126 | Date: September 30, 2010 | Change Request: 7133

SUBJECT: Counseling to Prevent Tobacco Use

EFFECTIVE DATE: AUGUST 25, 2010

IMPLEMENTATION DATE: JANUARY 3, 2011

I. GENERAL INFORMATION

A. Background: Tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs. Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1200 die prematurely each day from tobacco-related diseases. Annual smoking-attributable expenditures can be measured both in direct medical costs (\$96 billion) and in lost productivity (\$97 billion), but the results of national surveys have raised concerns that recent declines in smoking prevalence among U.S. adults may have come to an end. According to the U.S. Department of Health and Human Services (DHHS) Public Health Service (PHS) Clinical Practice Guideline on Treating Tobacco Use and Dependence (2008), 4.5 million adults over 65 years of age smoke cigarettes. Even smokers over age 65, however, can benefit greatly from abstinence, and older smokers who quit can reduce their risk of death from coronary heart disease, chronic obstructive lung disease and lung cancer, as well as decrease their risk of osteoporosis.

Medicare Part B (section 210.4 of the National Coverage Determination (NCD) Manual) already covers cessation counseling for individuals who use tobacco and have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-related disease. In November 2009, based upon authority to cover "additional preventive services" for Medicare beneficiaries if certain statutory requirements are met, the Centers for Medicare & Medicaid Services (CMS) initiated a new national coverage analysis to evaluate whether the existing evidence on counseling to prevent tobacco use is sufficient to extend national coverage for cessation counseling to those individuals who use tobacco but do not have signs or symptoms of tobacco-related disease. One of these statutory requirements is that the service be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the US Preventive Services Task Force (USPSTF).

- **B. Policy:** Effective for claims with dates of service on and after August 25, 2010, CMS will cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries:
- 1. Who use tobacco, regardless of whether they have signs or symptoms of tobacco-related disease;
- 2. Who are competent and alert at the time that counseling is provided; and
- 3. Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

The CMS will allow two individual tobacco cessation counseling attempts per year. Each attempt may include a maximum of four intermediate OR intensive sessions, with a total benefit covering up to 8 sessions per year per for a Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than 3 minutes but less than 10 minutes) or intensive (more than 10 minutes) cessation counseling sessions for each attempt.

Section 4104 of the Affordable Care Act provided for a waiver of the Medicare coinsurance and Part B deductible requirements for this service effective on or after January 1, 2011. Until that time, this service will be subject to the standard Medicare coinsurance and Part B deductible requirements.

II. **BUSINESS REQUIREMENTS TABLE**

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A	D	F	C	R		ared-	•		OTHER
		B	M E	I	A R	H H	F	Mainta M	ainers V	С	
		M	М		R	I	I	С	M	W	
		A	A		E		S S	S	S	F	
		C	C		R						
7133-03.1	Effective for claims with dates of service on and after	X		X	X	X	X	X			
	August 25, 2010, contractors shall pay for counseling to										
	prevent tobacco use services for hospitalized and										
	outpatient Medicare patients who meet the requirements										
	under Pub. 100-03, chapter 1, section 210.4.1, and										
	follow the claims processing instructions contained in										
	Pub. 100-04, chapter 18, section 150.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A /	D M	F I	C A	R H		nared- Mainta			OTHER
		B M A	E M A		R R I E R	H	F I S S	M C S	V M S	C W F	
			U								

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
7133-03.01	See companion CR 7133, Pub. 100-04 for detailed business requirements for this new benefit.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): William Larson, Coverage, 410-786-4639, William.larson@cms.hhs.gov, Wanda Belle, Coverage, 410-786-7491, wanda.belle@cms.hhs.gov, Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Tom Dorsey, Practitioner Claims Processing, 410-786-7434, Thomas.dorsey@cms.hhs.gov, Bill Ruiz, Institutional Claims Processing, 410-786-2123, William.Ruiz@cms.hhs.gov

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For Medicare Administrative Contractors (MACs), include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1) Coverage Determinations

Table of Contents (*Rev.126*, 09-30-10)

210.4.1 – Counseling to Prevent Tobacco Use (Effective August 25, 2010)

210.4.1 – Counseling to Prevent Tobacco Use (Effective August 25, 2010) (Rev.126, Issued: 09-30-10, Effective: 08-25-10, Implementation: 01-03-11)

A. General

Tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs. Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1,200 die prematurely each day from tobacco-related diseases. Annual smoking-attributable expenditures can be measured both in direct medical costs (\$96 billion) and in lost productivity (\$97 billion), but the results of national surveys have raised concerns that recent declines in smoking prevalence among U.S. adults may have come to an end. According to the U.S. Department of Health and Human Services (DHHS) Public Health Service (PHS) Clinical Practice Guideline on Treating Tobacco Use and Dependence (2008), 4.5 million adults over 65 years of age smoke cigarettes. Even smokers over age 65, however, can benefit greatly from abstinence, and older smokers who quit can reduce their risk of death from coronary heart disease, chronic obstructive lung disease and lung cancer, as well as decrease their risk of osteoporosis.

Medicare Part B (section 210.4 of the National Coverage Determination (NCD) Manual) already covers cessation counseling for individuals who use tobacco and have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-related disease. In November 2009, based upon authority to cover "additional preventive services" for Medicare beneficiaries if certain statutory requirements are met, the Centers for Medicare & Medicaid Services (CMS) initiated a new national coverage analysis to evaluate whether the existing evidence on counseling to prevent tobacco use is sufficient to extend national coverage for cessation counseling to those individuals who use tobacco but do not have signs or symptoms of tobacco-related disease. One of these statutory requirements is that the service be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the US Preventive Services Task Force (USPSTF).

B. Nationally Covered Indications

Effective for claims with dates of service on or after August 25, 2010, CMS will cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries

- 1. Who use tobacco, regardless of whether they have signs or symptoms of tobacco-related disease;
- 2. Who are competent and alert at the time that counseling is provided; and,
- 3. Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

Intermediate and intensive smoking cessation counseling services will be covered under Medicare Pat B when the above conditions of coverage are met, subject to frequency and other limitations. That is, similar to existing tobacco cessation counseling for symptomatic individuals, CMS will allow 2 individual tobacco cessation counseling attempts per 12-month

period. Each attempt may include a maximum of 4 intermediate OR intensive sessions, with a total benefit covering up to 8 sessions per 12-month period per Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than 3 minutes but less than 10 minutes), or intensive (more than 10 minutes) cessation counseling sessions for each attempt.

C. Nationally Non-Covered Indications

Inpatient hospital stays with the principal diagnosis of tobacco use disorder are not reasonable and necessary for the effective delivery of tobacco cessation counseling services. Therefore, we will not cover tobacco cessation services if tobacco cessation is the primary reason for the patient's hospital stay.

D. Other

Section 4104 of the Affordable Care Act provided for a waiver of the Medicare coinsurance and Part B deductible requirements for this service effective on or after January 1, 2011. Until that time, this service will continue to be subject to the standard Medicare coinsurance and Part B deductible requirements.

(This NCD last reviewed August 2010.)